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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,827	05/19/2006	Erik Andersen	4614-0189PUS1	5490

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EXAMINER

CARPENTER, WILLIAM R

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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09/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/560,827	Applicant(s) ANDERSEN ET AL.	
	Examiner WILLIAM CARPENTER	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Regarding Claim 1, Claim 1 recites the limitation "a larger extent of the second surface is associated with the tapered protrusion on the second surface". However, express support for this limitation could not be found in the specification as originally filed, nor can support for this limitation be inferred from the provided figures. As it is not clear to which extent of the second surface Applicant refers, and no dimensions have been provided as to allow Examiner to ascertain such a relationship, it is held that the above recited limitation is not supported by the disclosure as originally filed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 6, 7, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding Claim 1, Applicant recites the limitation "the passage slit having a larger extent at the first surface than the second surface such that the smaller extent of the passage slit is positioned on the concave portion at the first surface". This limitation renders the claim indefinite, as it is not clear how the passage slit can have "a larger extend at the first surface" while simultaneously "the smaller extent of the passage slit is positioned on the concave portion at the first surface". For the sake of prosecution it is believed that when Applicant initially filed the claims the "first surface" referred to surface (156) and the "second surface" referred to surface (160). However, upon amendment to the claims it would appear that Applicant has redefined the "first surface" to refer to surface (160) and the "second surface" to refer to surface (156). As such the first surface will be considered to be the surface comprising the protrusion and the second surface will be considered to be the surface comprising the concavity. Appropriate correction is required.

Further Regarding Claim 1, Applicant recites the limitation "a larger extent of the second surface is associated with the tapered protrusion on the second surface". This limitation renders the claim indefinite as it is not immediately clear to which feature of the device this limitation refers. It is presumed that Applicant intended to recite the claim as "a larger extent of the passage slit is associated with the tapered protrusion on the first surface". Appropriate correction is required.

Regarding Claims 6 and 7, Applicant recites the limitation "wherein at least a portion of one of the first and second end surfaces is concave". However, this limitation renders the claim indefinite as it is not clear how this claim further defines or

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distinguishes over the concave portion of the second surface positively claimed in Claim

1. Appropriate correction is required.

Regarding Claim 9, Applicant recites the limitation “in the area of said protrusion and **said** indentation...” [Formatting altered for emphasis]. However, this limitation is not proper as no indentation has previously been introduced with respect to Claim 1 or 9. For the sake of prosecution it was presumed that Claim 9 was intended to be dependent on Claim 8 which provides positive antecedent basis for a protrusion. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8. Claims 1-7 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,199,948 ("McPhee") in view of US Patent No. 5,149,327 ("Oshiyama").

Regarding Claims 1- 4, 11, and 12, MCPhee discloses a closure (15) for a valve of connector (13 and 17 in combination) of a hemostatic assembly (11), the connector comprising a longitudinally extending main section having a longitudinally extending through going passage, with the valve at the proximal end of the connector. MCPhee discloses the closure member to be formed a resilient rubber material (Column 3, Lines 31-32) having a second surface (35a) which comprises a concave portion (35) adapted to be engaged by a tubular member (47) which is configured to extend through the closure member, and an opposite first surface which comprises a protrusion (31) which extends into a longitudinal passage of the connector, wherein the protrusion is tapered such that the diameter of the proximal extent is greater than the diameter of the distal extend (Figure 2). MCPhee discloses the device to include at least one passage slit (33), being normally closed, and extending between the two end surfaces, the passage slit arranged to open by the tubular member inserted therethrough (Figure 5).

What MCPhee fails to explicitly disclose is that the passage slit should have a smaller extent on the first surface as compared to the extent on the second surface. However, Oshiyama discloses a similar resilient closure member (10A) used to form a valve of a hemostatic assembly. Oshiyama discloses that instead of a single slit, a plurality of passage slits (13A and 14A) should be provided, the slits having a smaller extent (17A and 15A) on the second ingress surface as compared to the extent (16A

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and 18A) on the first egress surface. Oshiyama discloses that these slits intersect to form a first, common point of contact on the first surface and extend radially outwardly from the point of contact at the first surface (Figure 2). Similarly the slits define a second, common point of contact on the second surface.

While Oshiyama does disclose the egress of the slit to be larger than the ingress, Oshiyama fails to explicitly disclose that the ingress should be at most $1/10^{\text{th}}$ the length of the egress. However, as Applicant has failed to explicitly disclose that this particular ratio solves any expressly stated problem or is anything more than one of the numerous configurations for the passage slit one having ordinary skill in the art at the time the invention was made would have found obvious to use, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the ingress to be at most $1/10^{\text{th}}$ the length of the egress, since it has been held that determining the workable or optimum range of a result effective variable requires only routine and customary skill in the art.

Oshiyama discloses that this configuration has the advantage of allowing easy insertion of even thick tubular members while providing a high liquid sealing characteristic (Column 7, Lines 24-26; Column 6, Line 57 – Column 7, Line 21). It would have been obvious for one having ordinary skill in the art at the time the invention was made to replace the single slit of the device of McPhee with a plurality of slits having an larger egress than ingress, as disclosed by Oshiyama, in order to allow the easy insertion of large tubular members while maintaining the integrity of the seal.

Regarding Claim 5, McPhee discloses that the first end surface and at least a portion of the second end surface (35a) define two substantially parallel planes (Figure 1), and wherein an axis extending between the first and second common point of contact, as modified in view of Oshiyama, is substantially perpendicular to the two planes.

Regarding Claims 6 and 7, McPhee discloses that a portion (35) of the second surface is concave.

Regarding Claim 13, McPhee discloses that the second surface of the closure member is oriented to face the proximal end of the connector (Figure 1).

Regarding Claims 14 and 15, McPhee discloses the device substantially as claimed except that the connector should be provided with side arm tubing for a side arm of the connector and including a stop cock for connection thereto. However, Oshiyama discloses a hemostatic assembly (50) having a connector (20) and a resilient closure member (23). Oshiyama discloses the connector to have a side arm (27) including side arm tubing (51) connected thereto and terminating in a stopcock (52) at the opposite end. Oshiyama discloses that such a configuration may be used to introduce liquid medicaments or collect blood. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the connector of the device of McPhee having a side arm and associated side arm tubing and stopcock, as disclosed by Oshiyama, in order to allow the infusion of fluid medicaments or the sampling of blood.

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9. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,199,948 ("McPhee") and US Patent No. 5,149,327 ("Oshiyama") as applied to Claim 1 above, and further in view of US Patent No. 5,114,408 ("Fleischhaker").

Regarding Claims 8-10, while MCPhee does disclose that a face of the closure does abut a proximal end surface (37) of the main section of the connector, MCPhee fails to disclose that the face should be provided with an integral protrusion corresponding to an indentation provided on the proximal end surface. However, Fleischhaker discloses a similar hemostatic assembly (Figure 1) comprising a connector (1) and a closure member (6). Fleischhaker discloses that a face of the closure member abuts the proximal end surface of the connector. To secure this abutment Fleischhaker discloses providing the proximal end face of the connector with protrusions/ribs (16) that correspond to indentations on the face of the abutting closure member, thereby forming a liquid tight periphery, holding the closure member in place.

While Fleischhaker discloses the protrusion to be on the proximal end surface of the connector and the indentation on the face of the closure member, it would have been obvious for one having ordinary skill in the art at the time the invention was made to reverse the relationship, since it has been held that the mere reversal of orientation the working parts of a device requires only routine and customary skill in the art. It would have been further obvious for one having ordinary skill in the art at the time the invention was made to provide the proximal end surface of the closure member and the face of the closure member of the device of MCPhee with a indentation and protrusion

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respectively, as disclosed by Fleischhaker, as to permit the resilient closure member to deform about the area of the protrusion and the indentation when the face and end surface are biased towards each other in order to provide a liquid tight seal about the outer periphery of the longitudinal passage at a proximal end thereof.

Response to Arguments

10. Applicant's arguments with respect to Claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
09/11/2008

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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